



[Billing code: 6750-01-S]

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act (PRA). The FTC seeks public comment on its proposal to extend through May 31, 2016 the current OMB clearance for information collection requirements contained in its Contact Lens Rule. That clearance expires on May 31, 2013.

DATES: Comments must be received by [insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comments part of the SUPPLEMENTARY INFORMATION section below.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to Alysia S. Bernstein, Attorney, and Bonnie McGregor, Federal Trade Investigator, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580, (202) 326-3289 (Bernstein) and (202) 326-2356 (McGregor).

SUPPLEMENTARY INFORMATION:

Proposed Information Collection Activities

Under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501-3520, federal agencies must get OMB approval for each collection of information they conduct, sponsor, or require. "Collection of information" means agency requests or requirements to submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by section 3506(c)(2)(A) of the PRA, the Federal Trade Commission (FTC) is providing this opportunity for public comment before requesting that OMB extend the existing PRA clearance for the information collection requirements associated with the Commission's Contact Lens Rule (Rule), 16 CFR Part 315 (OMB Control Number 3084-0127).

The FTC invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond. All comments must be received on or before [insert date 60 days after date of publication in the FEDERAL REGISTER].

The Rule was promulgated by the FTC pursuant to the Fairness to Contact Lens Consumers Act (FCLCA), Pub. L. 108-164 (Dec. 6, 2003), which was enacted to enable consumers to purchase contact lenses from the seller of their choice. The Rule became effective on August 2, 2004. As mandated by the FCLCA, the Rule requires the release

and verification of contact lens prescriptions and contains recordkeeping requirements applying to both prescribers and sellers of contact lenses.

Specifically, the Rule requires that prescribers provide a copy of the prescription to the consumer upon the completion of a contact lens fitting and verify or provide prescriptions to authorized third parties. The Rule also mandates that a contact lens seller may sell contact lenses only in accordance with a prescription that the seller either: (a) has received from the patient or prescriber; or (b) has verified through direct communication with the prescriber. In addition, the Rule imposes recordkeeping requirements on contact lens prescribers and sellers. For example, the Rule requires prescribers to document in their patients' records the medical reasons for setting a contact lens prescription expiration date of less than one year. The Rule requires contact lens sellers to maintain records for three years of all direct communications involved in obtaining verification of a contact lens prescription, as well as prescriptions, or copies thereof, which they receive directly from customers or prescribers.

The information retained under the Rule's recordkeeping requirements is used by the Commission to substantiate compliance with the Rule and may also provide a basis for the Commission to bring an enforcement action. Without the required records, it would be difficult either to ensure that entities are complying with the Rule's requirements or to bring enforcement actions based on violations of the Rule.

Burden Statement:

Commission staff estimates the paperwork burden of the FCLCA and Rule based on its knowledge of, and information from, the eye care industry. Staff believes there

will be some burden on individual prescribers to provide contact lens prescriptions, although it involves merely writing a few items of information onto a slip of paper and handing it to the patient, or perhaps mailing or faxing it to a third party. In addition, there will be some recordkeeping burden on contact lens sellers—including retaining prescriptions or records of “direct communications”—pertaining to each sale of contact lenses to consumers who received their original prescription from a third party prescriber.

No substantive provisions in the Rule have been amended or changed since staff’s prior submission to OMB.¹ Thus, the Rule’s disclosure and recordkeeping requirements remain the same.

Estimated total annual hours burden: 1,770,166 hours.

Based upon staff knowledge of the industry, this figure is derived by adding 633,333 disclosure hours for contact lens prescribers to 1,136,833 recordkeeping hours for contact lens sellers, for a combined industry total of 1,770,166 hours. This is higher than the estimates previously submitted to OMB (the similar figure was 850,000 hours in 2009); and is due to both an increase in the estimated number of contact lens wearers from 34 million (2008) to 38 million (2012) and staff’s belief that the percentage of sales in the industry that require obtaining or verifying a prescription is currently higher than what was previously estimated.

¹ The FTC most recently submitted clearance three years ago. 75 FR 19647 (Apr. 15, 2010) and 74 FR 68427 (Dec. 24, 2009).

As noted above, the number of contact lens wearers in the United States is estimated to be approximately 38 million.² Therefore, assuming an annual contact lens exam for each contact lens wearer, approximately 38 million people would receive a copy of their prescription each year under the Rule. At an estimated one minute per prescription, the annual time spent by prescribers complying with the disclosure requirement would be 633,333 hours. $[(38 \text{ million} \times 1 \text{ minute})/60 \text{ minutes} = 633,333.3 \text{ hours}]$

As required by the FCLCA, the Rule also imposes two recordkeeping requirements. First, prescribers must document the specific medical reasons for setting a contact lens prescription expiration date shorter than the one year minimum established by the FCLCA. This burden is likely to be nil because the requirement applies only in cases when the prescriber invokes the medical judgment exception, which is expected to occur infrequently, and prescribers are likely to record this information in the ordinary course of business as part of their patients' medical records. The OMB regulation that implements the PRA defines "burden" to exclude any effort that would be expended regardless of a regulatory requirement. 5 CFR 1320.3(B)(3)(2).

Second, the Rule requires contact lens sellers to maintain certain documents relating to contact lens sales. As noted above, a seller may sell contact lenses only in accordance with a prescription that the seller either (a) has received from the patient or prescriber, or (b) has verified through direct communication with the prescriber. The

² See Jason J. Nichols, Annual Report: Contact Lenses 2012, Contact Lens Spectrum, Jan. 2013, at 24.

FCLCA requires sellers to retain prescriptions and records of communications with prescribers relating to prescription verification for three years.

Staff believes that the burden of complying with this requirement is low. Sellers who seek verification of contact lens prescriptions must retain one or two records for each contact lens sale: either the relevant prescription itself, or the verification request and any response from the prescriber. Staff estimates that such recordkeeping will entail a maximum of five minutes per sale, including time spent preparing a file and actually filing the record(s).

According to recent survey data, approximately 35.9% of consumers who purchase contact lenses purchase those lenses from a source other than the doctor who originally wrote the prescription.³ This means that approximately 13,642,000 consumers—35.9% of the 38 million contact lens wearers in the United States—purchase their lenses from sellers other than the doctor who originally wrote their prescription.

At an estimated five minutes per sale to each of 13.642 million consumers, contact lens sellers will spend a total of 1,136,833 burden hours complying with the recordkeeping requirement. $[(13.642 \text{ million} \times 5 \text{ minutes}) / 60 \text{ minutes} = 1,136,833.3 \text{ hours}]$ This estimate likely overstates the actual burden, however, because it includes the time spent by sellers who already keep records pertaining to contact lens sales in the ordinary course of business. In addition, the estimate may overstate the time spent by

³ See VisionWatch, The Vision Council, Contact Lenses, 11A-C (March 2012) (Research Report); VisionWatch, The Vision Council, Contact Lenses, 11A-C (Sept. 2012) (Research Report). The average of the figures given for each six-month period is 35.9%.

sellers to the extent that records (*e.g.*, verification requests) are generated and stored automatically and electronically, which staff understands is the case for some larger online sellers.

Estimated labor costs: \$48,602,000 (rounded to the nearest thousand).

Commission staff derived labor costs by applying appropriate hourly cost figures to the burden hours described above. Staff estimates, based on information from the industry, that optometrists account for approximately 85% of prescribers. Consequently, for simplicity, staff will focus on their average hourly wage in estimating prescribers' labor cost burden.

According to Bureau of Labor Statistics from May 2011, salaried optometrists earn an average wage of \$51.79 per hour and general office clerks earn an average of \$13.90 per hour.⁴

With these categories of personnel, respectively, likely to perform the brunt of the disclosure (for optometrists) and recordkeeping (for office clerks) aspects of the Rule, estimated total labor cost attributable to the Rule would be approximately \$48.6 million.

$$[(\$51.79 \times 633,333.3 \text{ hours}) + (\$13.90 \times 1,136,833.3 \text{ hours}) = \$48,602,314]$$

The contact lens market is a multibillion dollar market; one recent survey estimates that contact lens sales totaled \$4,025,500,000 at the retail level between September 2011 and September 2012.⁵ Thus, the total labor cost burden estimate of

⁴ Press Release, Bureau of Labor Statistics, United States Department of Labor, Occupational Employment and Wages -- May 2011, Table 1 (March 27, 2012), *available at* <http://www.bls.gov/news.release/ocwage.htm>.

⁵ The Vision Council, Consumer Barometer, 2 (Sept. 2012) (Research Report). The market may, in fact, be larger; this number does not include dollars spent by consumers 17 years of age and younger.

\$48.6 million represents approximately 1.2% of the overall market.

Estimated annual non-labor cost burden: \$0 or minimal.

Staff believes that the Rule's disclosure and recordkeeping requirements impose negligible capital or other non-labor costs, as the affected entities are likely to have the necessary supplies and/or equipment already (*e.g.*, prescription pads, patients' medical charts, facsimile machines and paper, telephones, and recordkeeping facilities such as filing cabinets or other storage).

Request for Comments

You can file a comment online or on paper. Write "Contact Lens Rule: FTC File No. P054510" on your comment. Your comment – including your name and your state – will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at <http://www.ftc.gov/os/publiccomments.shtml>. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which is . . . privileged or

confidential,” as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, the Commission encourages you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/contactensrulepra>, by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov>, you also may file a comment through that website.

If you file your comment on paper, write “Contact Lens Rule: FTC File No. P054510” on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex J), 600 Pennsylvania Avenue, NW, Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at <http://www.ftc.gov> to read this Notice. The FTC Act and other laws that the Commission administers permit the collection of public

comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before [insert date 60 days after date of publication in the FEDERAL REGISTER]. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

Christian S. White,
Acting General Counsel.

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